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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Application of MELKER, et al.

Application No.: 20030139681 (10/054,619)

Examiner: CROSS, LATOYA

Date Filed: January 22, 2002

Group:

For: METHOD AND APPARATUS FOR MONITORING INTRAVENOUS (IV) DRUG
CONCENTRATION USING EXHALED BREATH

CERTIFICATE UNDER 37 CFR 1.8(a)

I hereby certify that this correspondence is being deposited
with the U.S. Postal Service as First Class mail in an envelope
addressed to the Commissioner for Patents, Washington, D.C.
20231, on August 20, 2004.

James D. Talton

DECLARATION

Assistant Commissioner for Patents
Washington, DC 20231

RECEIVED
AUG 25 2004

TECHNOLOGY CENTER R3700

Sir:

I, James David Talton, do hereby declare as follows:

1. I am an inventor of application 09/708,789 ('789), filed Nov. 8, 2000, now abandoned, which claims the benefit of U.S. Provisional Application No. 60/164,250, filed Nov. 8, 1999. The US application '789 claims benefit of PCT application, WO 01/34024, which is still in active prosecution. A continuation to '789, application 10/722,620 ('620) filed November 26, 2003, with inventors Melker, Lampotang, and Silverman, claims priority to the '789 application, but does not list me as an inventor. The related application 20030139681 ('681), filed January 22, 2002, with inventors Melker and Bjoraker, also does not list me as an inventor.

2. Following discussions with the University of Florida, the Assignee on the above mentioned '789, '620, and '681 patent applications, I called the examiner Latoya Cross to discuss the status of the '789 application. She confirmed that the '789 application had been abandoned by the University of Florida. Searching the USPTO website I found that the '681 application had been filed, with similar description of the invention, but that I had been excluded as an inventor.

3. In recent discussions with the University of Florida and its patent attorney Jeff Lloyd in July 2004 it was confirmed that I was believed to be an inventor on at least one of the claims (claim 4) of the '620 application. This email correspondence with Tony Palmieri of the University of Florida Office of Technology Licensing is appended as DOCUMENT 1. It was

stated that the University of Florida would remove this claim and retain the current inventor list for this application.

4. I am familiar with the original '250 provisional patent application, filed Nov. 8, 1999, and the '789 patent application and claims, of which I am an inventor. I am also familiar with the University of Florida invention disclosure filed prior to '250, of which I am also an inventor.

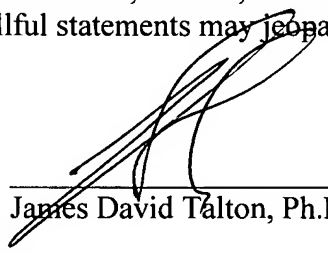
5. In a Cooperative Research Project (CRADA) between Nanosphere, Inc., and the Naval Research Laboratories (NRL) in Washington, DC, which began in February 2000, I was involved in the first sensor proof-of-concept results using common markers (menthol, camphor, and eucalyptus oil) as well as propofol. A data slide prepared in November 2000 by R. Andrew McGill following studies at the NRL is appended as DOCUMENT 2. It is my belief that I was involved in the conception of the '681 invention, partially from the fact that it is similar to the invention of the '789 patent application, and particularly since I was involved in the first *in vitro* vapor detection tests of propofol using a polymer-coated surface acoustic wave (SAW) sensor system.

6. Finally, I was involved in proof-of-concept animal studies on February 1st, 2001, involving infusion of propofol and detection of sampled breath levels using the NanobreathTM sensor system. Release of these confidential notes is withheld but were dated and signed in lab notebooks held by my company.

7. In conclusion, I declare, in my belief, that I am an inventor on US patent application 20030139681, Method and apparatus for monitoring intravenous (IV) drug concentration using exhaled breath.

8. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further these statements were made with the knowledge that the making of willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 8/20/04


James David Talton, Ph.D.

James D. Talton, Ph.D.

Document 1. (R) 8/20/04

From: Anthony Palmieri [ap3@rgp.ufl.edu]
Sent: Tuesday, July 13, 2004 2:21 PM
To: jtalton@nanotherapeutics.com
Cc: dlday@ufl.edu
Subject: RE: Breath patent UF 10189



Jim,

Upon further review, it is our position that the only claim that you might be a co-inventor on is a part of Claim 4, where the sensor is a SAW based device. Current research at UF on the device claimed in this application is not centered on SAW based technology. Therefore we have removed this part of the claim so that we do not incur the cost of prosecuting something we will not be commercializing. It is the opinion of our patent counsel that you are not a co-inventor on this application.

Tony

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Document 2 A 8/20/04

Order of Response and Magnitude Response
to Different Vapor

